

## P ENT COOPERATION TREA

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 17 April 2001 (17.04.01)	
<b>International application No.</b> PCT/US00/17076	<b>Applicant's or agent's file reference</b> MCA-460 PC
<b>International filing date (day/month/year)</b> 21 June 2000 (21.06.00)	<b>Priority date (day/month/year)</b> 22 June 1999 (22.06.99)
<b>Applicant</b> BARTLETT, Andrew et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

22 January 2001 (22.01.01)

☐ in a notice effecting later election filed with the International Bureau on:
2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b>  Kiwa Mpay Telephone No.: (41-22) 338.83.38
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CA

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

MILLIPORE CORPORATION  
Attn. HUBBARD, John Dana  
80 Ashby Road  
Bedford, Massachusetts 01730  
UNITED STATES OF AMERICA

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

25/04/2001

Applicant's or agent's file reference

MCA-460 PC

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US 00/17076

International filing date  
(day/month/year)

21/06/2000

Applicant

MILLIPORE CORPORATION et al.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Toñi Muñoz-Manneken

MCA 4-30-01

Docketed By:

Due Date:

Reminder (s):

Action Due:

In Database

ART 19-6-250

5-250

NO Sep. U.S. case

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

## INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

### What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

**The following examples illustrate the manner in which amendments must be explained in the accompanying letter:**

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

**"Statement under article 19(1)" (Rule 46.4)**

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

**It must be in the language in which the international application is to be published.**

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

**Consequence if a demand for international preliminary examination has already been filed**

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

**Consequence with regard to translation of the international application for entry into the national phase**

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>MCA-460 PC</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 00/ 17076</b>	International filing date (day/month/year) <b>21/06/2000</b>	(Earliest) Priority Date (day/month/year) <b>22/06/1999</b>
Applicant <b>MILLIPORE CORPORATION et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
2. ☐ **Certain claims were found unsearchable** (See Box I).
3. ☒ **Unity of invention is lacking** (see Box II).

### 4. With regard to the **title**,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established by this Authority to read as follows:  
**FILTRATION DEVICES COMPRISING A SEALING GASKET**

### 5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

### 6. The figure of the **drawings** to be published with the abstract is Figure No.

- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.
- ☒ None of the figures.

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1 3 23-26

a filtration device

2. Claims: 2 4-22

a feed screen (for a filter device) or a filtration module

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 B01D35/30 B01D63/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 B01D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  
 EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 230 812 A (WILLIAMS) 27 July 1993 (1993-07-27) column 2, line 5 -column 5, line 7	1, 3, 24
X	EP 0 470 440 A (GILARDINI S.P.A.) 12 February 1992 (1992-02-12) column 2, line 35 -column 5, line 52	1, 3, 23-26
X	US 5 034 124 A (KOPF) 23 July 1991 (1991-07-23) column 17, line 25 -column 18, line 5 column 19, line 56 -column 20, line 14	1-26
X	US 5 445 737 A (ONDRICK) 29 August 1995 (1995-08-29) column 3, line 40 -column 5, line 37	1-26

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

17 April 2001

Date of mailing of the international search report

25. 04. 2001

Name and mailing address of the ISA

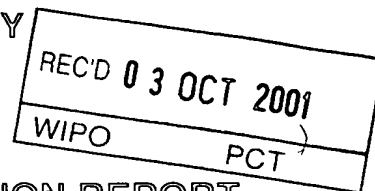
European Patent Office, P.B. 5818 Patentlaan 2  
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 Fax: (+31-70) 340-3016

Authorized officer

Doolan, G



Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5230812	A	27-07-1993	AU 5717594 A EP 0656805 A WO 9403259 A	03-03-1994 14-06-1995 17-02-1994
EP 470440	A	12-02-1992	IT 1240537 B AT 105049 T DE 69101816 D DE 69101816 T DK 470440 T ES 2056530 T US 5259953 A	17-12-1993 15-05-1994 01-06-1994 25-08-1994 11-07-1994 01-10-1994 09-11-1993
US 5034124	A	23-07-1991	US 4882050 A US 5342517 A WO 9001981 A US 5049268 A US 5232589 A	21-11-1989 30-08-1994 08-03-1990 17-09-1991 03-08-1993
US 5445737	A	29-08-1995	US 5217612 A	08-06-1993



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference <b>MCA-460 PC</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/US00/17076</b>	International filing date (day/month/year) <b>21/06/2000</b>	Priority date (day/month/year) <b>22/06/1999</b>
International Patent Classification (IPC) or national classification and IPC <b>B01D35/30</b>		
Applicant <b>MILLIPORE CORPORATION et al.</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand <b>22/01/2001</b>	Date of completion of this report <b>01.10.2001</b>
Name and mailing address of the international preliminary examining authority:  <b>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</b>	Authorized officer <b>Katsoulas, K</b> Telephone No. +49 89 2399 8613 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/17076

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

### Description, pages:

1,4-11,13 as originally filed

2,3,12 as received on 03/09/2001 with letter of 03/09/2001

### Claims, No.:

1-14 as received on 03/09/2001 with letter of 03/09/2001

### Drawings, sheets:

1/7,2/7,4/7-7/7 as originally filed

3/7 as received on 03/09/2001 with letter of 03/09/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US00/17076

4. The amendments have resulted in the cancellation of:

- ☐ the description,      pages:
- ☐ the claims,      Nos.:
- ☐ the drawings,      sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	3-5,7-14
	No:	Claims	1,2,6
Inventive step (IS)	Yes:	Claims	3-5,9-14
	No:	Claims	7,8
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

**2. Citations and explanations  
see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

D1: US-A-5824217; D2: US-A-5034124; D3: US-A-5445737

**Ad Section V:**

1. D1 discloses (cf. fig. 4, col. 4 lines 7-19) a filtration device comprising multiple filter layers (eg. filtrate spacer (14)) with openings (28), said openings having injection molded in-place thermoplastic sealing rim (15) around said openings. It follows that claims 1, 2 and 6 are not novel in view of D1 (Art. 33(2) PCT).
2. Claim 3 essentially differs from the disclosure of fig. 4 in D1 in that the sealing means is in the form of a gasket which has a thickness greater than that of the filtrate layer/screen. Although the same document provides some information as to gasket-like, injection molded in-place thermoplastic raised ribs (cf. fig. 1, rib 9), there is no indication that the thickness of said gasket exceeds that of the screen. Given that no relevant information to this point is available from the remaining art, claim 3 is not obvious. Thus, Art. 33(3) PCT is fulfilled. This conclusion extends also to claims 4, 5 and 9-14.
3. For the particular shapes of the sealing means/gasket of claims 7 and 8 no inventive step can be acknowledged (Art. 33(3) PCT).

**Ad Section VIII:**

1. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.
2. Claims 4 and 5 are not supported by the description (Art. 6). More importantly, contrary to the teachings of claim 3, none of the indicated embodiments in the figures or the example show a gasket height exceeding that of the screen. It follows that, in case claim 3 is regarded as the main claim, extensive unclarity results.

MCA-460 PC

Some modules have been sealed by injection molding complete cassettes into a uniform device, see US 5,824,217. However, to use these modules one needs to acquire new manifold equipment that is an expensive capital investment. Most cassettes use a stacked manifold design held between two liquid impervious holder plates, typically made of stainless steel. The cassette modules typically have the filtrate side sealed from the retentate side of the cassette by adhesives, in particular epoxy or urethane adhesives. In addition to using the adhesive as the sealing means, it is also applied around one or more of the fluid ports, in particular the feed screen port to create a gasket that separates the feed port from the retentate and/or filtrate ports. At the current time, such gaskets are simply the same height as the screen itself and for many applications this has been sufficient. The system relies upon a compression seal to maintain integrity and prevent leakage between the various ports.

However, in some processes this type of seal is not sufficient. For example where the process calls for the use of alternating of hot and cold fluid cycles, it has been found that the seal is often insufficient and tends to leak. Likewise, when using compressible membranes such as reinforced composite cellulosic membranes, especially at higher pressures ( $>344.7 \text{ kPa}$ ) ( $>50 \text{ psi}$ ), the seal fails due to the compression of the membrane by the pressure of the fluid which allows for leakage.

In all three formats, the above methods of providing a seal or gasket have been less than satisfactory.

Adhesives are undesirable since they have limited chemical compatibility, are a source of significant extractable species, introduce process control difficulties, impose bond strength limitations, impose use temperature limitations and increase process cycle time.

Direct heat sealing wherein a heating element contacts a material which flows to form a seal is undesirable since its use imposes a limitation upon the thickness of the material being heat sealed. This results in a material reduction of the number of layers that can be present in a given volume of the filtration device, thereby undesirably reducing the filtration capacity of the device. In addition, direct heat sealing is undesirable because it requires multiple steps, imposes material compatibility limitations and requires a substrate to effect direct heat sealing of filtration elements.

Solvent bonding is undesirable since solvents impose environmental limitations on liquids to be filtered.

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MILLIPORE CORPORATION et al

<INSERT> into page 3.

<US-A-5034124 describes a filter plate element and a filter comprising such element. The filter plate is longitudinally partitioned between its inlet and outlet ends and has liquid feed and collection troughs at the respective ends. A gasket element is disposed in a groove formed in a top surface of the plate to ensure positive liquid-tight sealing of the plate against a filter element.

US-A-5445737 describes an apparatus for diffusion analysis in which an anion exchange membrane is sandwiched between upper and lower stacks of gaskets provided with holes forming chambers when the gaskets are aligned in superposition.

#### SUMMARY AND OBJECTS OF THE INVENTION

The present invention provides a filtration device as defined in claim 1 and a filtration module defined in claim 9 employing such filtration devices as feed and filtrate screens. Preferred embodiments are defined in the dependent claims.>

MCA-460 PC

In addition, the use of materials such as polysilicone based materials as sealing materials, O-rings or gaskets is undesirable as they absorb a portion of a feed being filtered into their structure and then allow the absorbed material to be desorbed into subsequently filtered samples thereby contaminating them. Additionally, these free standing gaskets often fall out of the device during installation or repair or replacement and often are improperly seated which causes them to leak. Moreover, loose fitting seals such as O-rings create dead space behind the gasket sealing surface (such as between the inner wall of the O-ring and the wall of the filter housing to which it is attached). This dead space is a breeding ground for bacteria, molds, viruses and yeasts, all of which compromise the sterility and integrity of the seal and the filtration device.

What is required is a better material and method for the construction of sealing materials, O-rings and gaskets for all of these devices.

&lt;insert&gt;

#### SUMMARY AND OBJECTS OF THE INVENTION

The present invention relates to the formation of a seal around a filtration element to be sealed, such as one or more fluid ports in a filtration module. The use of thermoplastic materials, especially those that can be molded, preferably injection molded in place are preferred as it forms an integral, sanitary gasket or seal. The claimed materials are low in extractables and absorption/desorption of filtration fluids making them cleaner to use and ensuring that the sealing material does not add or remove any constituent of the fluid being filtered other than that desired by the filter action of the device (such as particulates, bacteria and viruses). Moreover, in the preferred molded in place embodiments, it prevents the seal from moving or being improperly aligned upon sealing ensuring that the seal is always consistently the same. Lastly, when using it in the preferred molded in place embodiments, the seal has no dead space behind it in which microorganisms might otherwise grow.

In a cassette device, the seal is formed on at least one side and preferably on both sides of the component such as a screen and is proud of or raised above the surface of the component. Preferably, the seal is molded to the component, more preferably it is injection molded to the component. The seal maybe formed of any elastomeric material such as a thermoplastic polymer, copolymer or terpolymer, thermoplastic elastomers, thermosets such as urethane, especially closed cell foamed urethane, and rubber, both natural and synthetic. The molded seal provides better sealing, allows for a variation in heights and geometries, in



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## EXAMPLE 1

A TFF module was made with a feed screen having an injection molded thermoplastic elastomeric gasket made from Santoprene® 80 durometer elastomer and 0.127 mm (.005 inch) in height from each side of the screen. One layer of a composite regenerated cellulose membrane, PL composite, a relatively easily compressible membrane available from Millipore Corporation, was used in the module.

A comparison module, known as a PELLICON® Maxi cassette, available from Millipore Corporation of Bedford, Massachusetts was constructed similarly to the one above, except that the feed screen seal of standard epoxy was used. This seal was flush with the surface of the screen.

Both were tested in a PELLICON® SS benchtop manifold, available from Millipore Corporation of Bedford, Massachusetts at 350 inlbs torque. Each was exposed to a series of 5 alternating cold/hot cycles using water as the fluid. The hot cycle was at a feed pressure of 413.7 kPa (60 psi) and then a retentate pressure of 241.2 kPa (35 psi) at 50°C for two hours. The cold cycle was static storage in a refrigerator at 5°C for 18 hours. Integrity of the seal in each cassette was tested at 68.9 kPa (10 psi) intervals up to 758.4 kPa (110 psi) between each cycle.

The integrity results were plotted in the graph of Figure 10 for both devices. As can be clearly seen the molded gasket device maintained its integrity throughout the test. The traditional cassette failed to achieve the high initial pressure resistance of the module of the (551.5 vs 758.4 kPa) present invention (80 vs 110psi) and it exhibited decreased sealing ability with increasing cycles.

The present invention has several advantages over the currently available devices.

First and foremost, it allows for the use of more compressible membranes than has been possible before, such as composite cellulose membranes. These membranes are highly efficient but due to their structure are easily compressible causing leakage to occur. The present invention overcomes the sealing problem created by such membranes thereby allowing for an entire new class of membranes to be used in filtration devices.

Second, it allows for the use of higher pressures in these applications, either with the traditional membranes or the newer more compressible membranes. Likewise, it is resilient in alternating hot/cold cycles which are quite common in filtration applications (cold for filtration, hot for inter batch cleaning). As the data clearly shows such thermal cycling has no effect on the performance of the device utilizing the current invention.

PCT/US00/17076  
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Claims

1. A filtration device comprising one or more filter layers and one or more openings (3,5,7;13,15,17;23,24,25), at least one (3;13;24) of said openings having a sealing means (9;19) for establishing a liquid tight seal around said opening(s)  
5 (3;13;24), characterized in that said sealing means (9;19) is molded in place and is an elastomeric material selected from the group consisting of thermoplastics, thermoplastic elastomers, thermoset elastomers and rubber, natural and synthetic.

10 2. The filtration device of claim 1 wherein the sealing means is in a form selected from the group consisting of a gasket, an O-ring, a sealing device and a sealing rim.

15 3. The filtration device of claim 2, wherein said one or more filter layers form a feed screen (20) or filtrate screen for a filter device, which feed/filtrate screen contains a plurality of said openings forming ports, said feed/filtrate screen having a relatively uniform thickness and a series of  
20 two or more ports (23,24,25) along at least one of its peripheral edges, at least one (23) of said ports having said sealing means in the form of a gasket which has a thickness greater than that of the feed/filtrate screen and said  
25 thickness of said gasket extends from at least one side of said feed/filtrate screen.

30 4. The filtration device of claim 2 or 3 wherein the gasket extends from about 0.0254 to about 0.381 mm (about 0.001 to about 0.015 inch) above at least one side of the feed/filtrate screen.

5. The filtration device of claim 4 wherein the gasket extends at least 0.0254 mm (0.001 inch), preferably at least 0.0508 mm (0.002 inch), preferably at least 0.127 mm (0.005 inch) above at least one side of the feed/filtrate screen.

5

6. The filtration device of any one of claims 1 to 5 wherein the sealing means/gasket is formed by injection molding.

10

7. The filtration device of any one of claims 1 to 6 wherein the sealing means/gasket is in a shape selected from the group consisting of a circle, oval and polygon.

15

8. The filtration device of claim 7 wherein the gasket is in the shape of a polygon and the polygon is selected from the group consisting of triangles, rectangles, pentagons, hexagons, heptagons, octagons, nonagons and decagons.

20

9. A filtration module comprising:

at least one membrane layer (33),

at least one feed screen (31) formed by a filtration device as defined in any one of claims 3 to 8, and

25

at least one filtrate screen (32) by a filtration device as defined in any one of claims 3 to 8, said feed screen (31) and said filtrate screen (32) being arranged on opposite sides of the membrane layer (33) to insure fluid flows

30

through a port on the feed screen (31) into the feed screen (31), from the feed screen (31) through the membrane layer (33) and into the filtrate screen (32) and through the one or more ports of the filtrate screen (32) to an exit from the module.

35

10. The filtration module of claim 9 wherein the height of the gasket is used to vary the channel height of the feed screen (31).

11. The filtration module of claim 9 wherein the height of the gasket is used to vary the channel height of the filtrate screen (32).

5 12. The filtration module of any one of claims 9 to 11 wherein the module is capable of withstanding pressures of from about 344.7 to about 758.4 kPa (from about 50 to about 110 psi) without leaking.

10 13. The filtration module of any one of claims 9 to 12 wherein the membrane layer (33) is made of a material selected from the group consisting of olefins, metallocene olefinic polymers, PFA, MFA, PTFE, polycarbonate, vinyl copolymers, polyamides, polyesters, cellulose, cellulose acetate, regenerated cellulose, cellulose composites, 15 polysulphone, polyethersulphone, polyarylsulphone, polyphenylsulphone, polyacrylonitrile, polyvinylidene fluoride (PVDF), and blends thereof.

20 14. The filtration module of any one of claims 9 to 13 wherein one or more sealing rims is/are formed upon the surface of an endcap layer.

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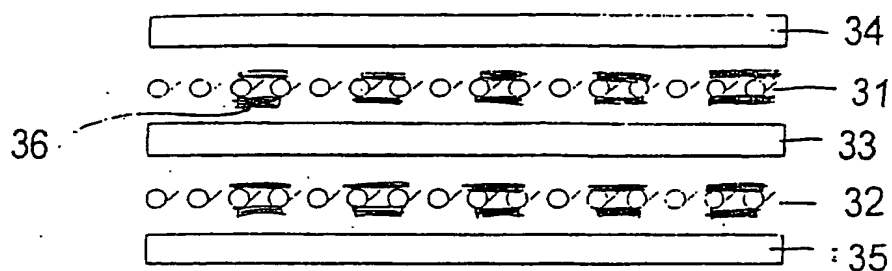


Figure 4

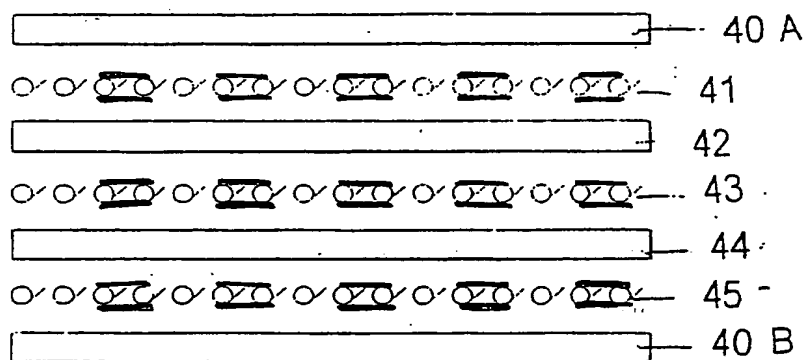


Figure 5

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(54) Title: **FILTRATION DEVICES COMPRISING A SEALING GASKET**

(57) Abstract: The present invention relates to the formation of a gasket, sealing area or O-ring, such as a gasket on a screen for a filtration module such as a TFF or NF cassette or an O-ring on the outlet of a filter cartridge wherein the seal is proud of at least one surface of the screen. Preferably, the seal is molded to the filter component, more preferably it is injection molded to the component. The seal may be formed of any elastomeric material such as thermoplastic, thermoplastic elastomers, thermosets and rubber, both natural and synthetic. The molded seal provides better sealing, allows for a variation in heights and geometries, and provides better cleanliness and lower extractables than the currently used adhesives or conventional gaskets or O-rings.

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**(57) Abstract:** The present invention relates to the formation of a gasket, sealing area or O-ring, such as a gasket on a screen for a filtration module such as a TFF or NF cassette or an O-ring on the outlet of a filter cartridge wherein the seal is proud of at least one surface of the screen. Preferably, the seal is molded to the filter component, more preferably it is injection molded to the component. The seal may be formed of any elastomeric material such as thermoplastic, thermoplastic elastomers, thermosets and rubber, both natural and synthetic. The molded seal provides better sealing, allows for a variation in heights and geometries, and provides better cleanliness and lower extractables than the currently used adhesives or conventional gaskets or O-rings.

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**FILTRATION DEVICES COMPRISING A SEALING GASKET**

The present invention relates to a sealing gasket for filtration devices. More particularly, it relates to the use of an integrally formed seal on or in a filtration device.

**BACKGROUND OF THE INVENTION**

The use of filtration devices is well known. Typically, these are used to filter liquids that contain various molecules that are desired to be removed from the liquid. Three basic designs are used. A flat sheet disk-shaped membrane in a holder, a cylindrical (pleated or unpleated or spiral wound) cartridge and a cassette with one or more flat filters.

In the disk membrane format, a membrane is held in a liquid tight arrangement about the periphery between a top and bottom holder plate. The seal is formed by flat surfaces of the holders, a knife edge arrangement on the holder surfaces on one or both sides of the membrane.

In the cartridge format, silicone gaskets, adhesives such as epoxies or urethanes, heat sealing or solvent bonding methods are often used to form the liquid tight seal between the core and the outlet, the ends of the filter element such as the attachment of end caps to one or both ends of a pleated filter, and other places where a liquid tight seal is required.

In cassette formats, the liquids are filtered within a plurality of filter modules that are stacked between manifolds or individually sealed to a manifold plate. Each module contains one or more filter layers separated by appropriate spacers layers such as screens and an impermeable outer layer on each outer surface of the module. At one or both ends of the modules are a series of ports that permit liquid feed to flow into the apparatus as well as filtrate and retentate to flow from the apparatus. It may be run in either a tangential flow (TFF, including HPTFF) manner or in a dead end or normal flow (NF) manner.

In a TFF operation, a fluid is fed from the feed port(s) to the space between the feed screen and filter and flowed across the face of the filter in a direction tangential to the flow of filtrate through the filter.

In a NF operation fluid is flowed directly at the filter surface and that fluid which is capable of passing through the membrane does so and the rest is left on the upstream side of the membrane.



Some modules have been sealed by injection molding complete cassettes into a uniform device, see US 5,824,217. However, to use these modules one needs to acquire new manifold equipment that is an expensive capital investment. Most cassettes use a stacked manifold design held between two liquid impervious holder plates, typically made of stainless steel. The cassette modules typically have the filtrate side sealed from the retentate side of the cassette by adhesives, in particular epoxy or urethane adhesives. In addition to using the adhesive as the sealing means, it is also applied around one or more of the fluid ports, in particular the feed screen port to create a gasket that separates the feed port from the retentate and/or filtrate ports. At the current time, such gaskets are simply the same height as the screen itself and for many applications this has been sufficient. The system relies upon a compression seal to maintain integrity and prevent leakage between the various ports.

However, in some processes this type of seal is not sufficient. For example where the process calls for the use of alternating of hot and cold fluid cycles, it has been found that the seal is often insufficient and tends to leak. Likewise, when using compressible membranes such as reinforced composite cellulosic membranes, especially at higher pressures (>50psi), the seal fails due to the compression of the membrane by the pressure of the fluid which allows for leakage.

In all three formats, the above methods of providing a seal or gasket have been less than satisfactory.

Adhesives are undesirable since they have limited chemical compatibility, are a source of significant extractable species, introduce process control difficulties, impose bond strength limitations, impose use temperature limitations and increase process cycle time.

Direct heat sealing wherein a heating element contacts a material which flows to form a seal is undesirable since its use imposes a limitation upon the thickness of the material being heat sealed. This results in a material reduction of the number of layers that can be present in a given volume of the filtration device, thereby undesirably reducing the filtration capacity of the device. In addition, direct heat sealing is undesirable because it requires multiple steps, imposes material compatibility limitations and requires a substrate to effect direct heat sealing of filtration elements.

Solvent bonding is undesirable since solvents impose environmental limitations on liquids to be filtered.

In addition, the use of materials such as polysilicone based materials as sealing materials, O-rings or gaskets is undesirable as they absorb a portion of a feed being filtered into their structure and then allow the absorbed material to be desorbed into subsequently filtered samples thereby contaminating them. Additionally, these free standing gaskets often fall out of the device during installation or repair or replacement and often are improperly seated which causes them to leak. Moreover, loose fitting seals such as O-rings create dead space behind the gasket sealing surface (such as between the inner wall of the O-ring and the wall of the filter housing to which it is attached). This dead space is a breeding ground for bacteria, molds, viruses and yeasts, all of which compromise the sterility and integrity of the seal and the filtration device.

What is required is a better material and method for the construction of sealing materials, O-rings and gaskets for all of these devices.

#### SUMMARY AND OBJECTS OF THE INVENTION

The present invention relates to the formation of a seal around a filtration element to be sealed, such as one or more fluid ports in a filtration module. The use of thermoplastic materials, especially those that can be molded, preferably injection molded in place are preferred as it forms an integral, sanitary gasket or seal. The claimed materials are low in extractables and absorption/desorption of filtration fluids making them cleaner to use and ensuring that the sealing material does not add or remove any constituent of the fluid being filtered other than that desired by the filter action of the device (such as particulates, bacteria and viruses). Moreover, in the preferred molded in place embodiments, it prevents the seal from moving or being improperly aligned upon sealing ensuring that the seal is always consistently the same. Lastly, when using it in the preferred molded in place embodiments, the seal has no dead space behind it in which microorganisms might otherwise grow.

In a cassette device, the seal is formed on at least one side and preferably on both sides of the component such as a screen and is proud of or raised above the surface of the component. Preferably, the seal is molded to the component, more preferably it is injection molded to the component. The seal maybe formed of any elastomeric material such as a thermoplastic polymer, copolymer or terpolymer, thermoplastic elastomers, thermosets such as urethane, especially closed cell foamed urethane, and rubber, both natural and synthetic. The molded seal provides better sealing, allows for a variation in heights and geometries, in

cassettes the use of more open screens, in some cases the elimination of a screen per se via the use of a molded rim of seal which forms an open space which acts as the screen and provides better cleanliness and lower extractables than the currently used adhesives.

It is an object of the present invention to provide a seal for a filter device comprised of a thermoplastic elastomer.

It is a further object of the present invention to provide a sealing means for a filtration device wherein the sealing means is formed of a thermoplastic elastomer that is molded in place on to a filter device.

It is another object of the present invention to provide a filtration module comprising at least one membrane layer, at least one feed screen layer and at least one filtrate screen, said at least one feed screen layer and said at least one filtrate layer having one or more ports formed in at least one of its edges and said layers being arranged on opposite sides of the membrane to insure fluid flows through a port on the feed screen layer into the feed screen layer, from the feed screen layer through the membrane and into the filtrate layer and through the one or more ports of the filtrate layer to an exit from the module, wherein the one or more ports of at least the feed screen and filtrate layer contain a molded seal which has a thickness greater than that of the screen and said thickness of said seal extends from at least one side of said layer.

It is a further object of the present invention to provide a filtration module comprising two outermost end cap layers which are impermeable to liquids and can be either metal or plastic holders which retain the module in place or plastic films which form the out layers of the module, one or more screen layers inside of the end caps, one or more filter layers inside the one or more screen layers, wherein at least one screen layer is a feed layer and contains a series of one or more feed stream ports in at least one of its peripheral edges, said feed stream ports being sealed by a molded seal which has a thickness greater than that of the screen and said thickness of said seal extends from at least one side of said screen.

#### IN THE DRAWINGS

Figure 1 shows a cross sectional view of a first embodiment of the present invention.

Figure 2 shows a cross sectional view of a second embodiment of the present invention.

Figure 3 shows a planar top view of either the first or second embodiments as shown in Figures 1 and 2.

Figure 4 shows the second embodiment of the present invention in a TFF module in cross sectional view.

Figure 5 shows another embodiment of the present invention in a TFF module in cross sectional view.

Figure 6 shows another embodiment of the present invention designed specifically in a normal flow (NF) configuration.

Figure 7 shows an endcap layer with an injection molded rim which in conjunction with an adjacent layer forms an open volume or space which acts as a screen according to the teachings of the present invention.

Figure 8 the use of gaskets according to the present invention in conjunction with connecting a filter device to the manifold plates of a cassette format.

Figure 9 shows a cartridge in which the silicone O-rings are replaced by the thermoplastic elastomer O-rings of the present invention.

Figure 10 shows a graph of the test results of Example 1.

## DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a sealing device such as a potting of a membrane, a seal edge on a membrane or a screen or a support layer surrounding the membrane or other component of a filter device, a gasket on a membrane port or outer edge or a screen port, an O-ring and other similar sealing components typically used in the manufacture of filtration devices.

The present invention uses selected materials for the sealing devices which have an ease of formation and application, low extractables, low absorption/desorption of components from the fluid being filtered. These materials include but are not limited to any elastomeric material such as a thermoplastic polymer, copolymer or terpolymer, thermoplastic elastomers, thermosets such as urethanes, especially closed cell foamed urethane, and rubber, both natural and synthetic.

In a preferred embodiment, the sealing device is injection or insert molded or otherwise integrally formed (by bonding, etc) to a component of the device, especially a plastic or other comparable material (glass mesh, woven fabric, etc.) to which the seal can bond and be

retained. In this way, one obtains an integral seal on the device which has several advantages in the ease of assembly and use, the assurance that the seal is always retained at the right location and cannot be mis-aligned or mis-sealed. Additionally, in these molded in place embodiments, the seal eliminates any dead space between the seal and the filter component to which it is bonded in which a microorganism such as a bacteria, yeast, mold or virus could otherwise grow and threaten the integrity and sanitary condition of the filter.

The present invention will now be explained in relation to several of the preferred embodiments, in particular in relation to an embodiment of the invention used on screens of a cassette type filtration device. However, through these illustrations, it is not meant to limit the invention to those particular embodiments.

Figure 1 shows a first embodiment of the present invention. It shows a feedscreen for a cassette filtration device. The feedscreen 1 has a series of ports 3, 5 and 7 which correspond to the feed, retentate and filtrate ports of the filtration device. As shown, the ports 3 have a gasket 9 formed around them to isolate them from the other ports. In this embodiment, the ports 3 are the filtrate ports of the feed screen so as to keep feed fluid separate from the filtrate. As shown, the gaskets 9 are formed through the screen and are proud or raised above the surface of the screen on one side only.

Figure 2 shows a second embodiment of the present invention. The feedscreen 11 has a series of ports 13, 15 and 17 that correspond to the feed, retentate and filtrate ports of the device. As shown, the ports 13 have a gasket 19 formed around them to isolate them from the other ports. As shown it is formed through the screen and is proud or raised above both major surfaces of the screen.

Figure 3 shows a planar top down view of either embodiment of Figures 1 or 2. As shown, a feed screen 20 has a feed side 21 and a retentate side 22. Fluid flows across the screen from the feed side 21 to the retentate side 22. There are five ungasketed feed ports 23 and four gasketed filtrate ports 24 on the feed side 21. Likewise there are four gasketed filtrate ports 24 and five ungasketed retentate ports 25 on the retentate side 22 of the screen 20. The gaskets surround and isolate the selected ports 24 from the other ports 23, 25. For a filtrate screen, the gaskets would be formed around the feed and retentate ports and the filtrate ports would left ungasketed.

While shown as a circular design, it is understood that the gasket merely needs to surround the fluid port and may be of any geometric design such as irregular, circular, oval,

ellipsoid, triangular or polygonal (square, rectangular, pentagonal, hexagonal, octagonal, decagonal, etc). The design selected is at the discretion of the designer so long as it doesn't interfere with any function of the device.

Figure 4 shows a cross section of a filtration module according to the present invention in its simpler form. A feed screen 31 and a filtrate screen 32 are positioned on opposite sides of a membrane 33. A first and second endcap layer 34 and 35 are located adjacent to and outside of the screens 31 and 32 to complete the package. The endcaps 34 and 35 may be the endplates of the filtration device such as stainless steel or plastic plates or separate layers formed as part of the module as described in US Patent 5,824,217 the teachings of which are herein incorporated by reference in its entirety. As shown, the gaskets 36 maintain the seal between the feed screen 31 and the gasket 36 and filtrate screen 32 and gasket 36 respectively for the desired ports. In this embodiment, fluid flows into the feed screen 31 through one or more non-gasketed ports formed in the screen 31 and which are connected to a source of fluid to be filtered. A portion of the fluid passes through the membrane 33 and the filtrate is removed from the module from one or more ports formed in the filtrate screen 32.

Figure 5 shows a cross section of a TFF module according to the present invention in a preferred form. The outer portions of the module are comprised of a first and second endcap layers 40 A and B. A first feed screen 41 is positioned inward of and adjacent to the endcap layer 40A. A first membrane layer 42 is positioned inward of and adjacent to the first feedscreen 41. Inward of that is a filtrate screen 43. Below that is a second membrane layer 44 followed by a second feedscreen 45 and the other endcap 40B which forms the other outer end of the module. Fluid flows from the feed screens 41 and 45 through one or more feed ports and through the membranes 42 and 44 to the filtrate screen 43. From there, the fluid is removed for further processing.

Figure 6 shows a NF or normal flow module. In this module, a feed screen 51 has one or more ports 52 located on one end of the screen. Fluid enters through these ports and a portion passes through the membrane 53 and is collected in the filtrate screen 54. The fluid which does not pass through the membrane remains upstream of the membrane as the retentate port 55 as shown has been sealed so as to prevent any tangential flow. The filtrate exits the device through one or more filtrate ports 56 formed on the end of the filtrate screen 54 opposite of the open port(s) 52 of the feed screen 51. The one or more filtrate ports 56 below

the open feed ports 52 have been also been sealed to prevent any channeling or tangential flow from occurring.

If desired, other arrangements may be made, such as using a central feedscreen and outer permeate and/or filtrate screens, additional filter layers, etc. Numerous variations can be made to combine the membranes and spacer (feed and retentate screen) layers to form workable devices. Additionally, the screens and modules of the present invention may as discussed above be used in tangential flow filtration devices or in dead end or normal flow filtration devices. See U.S. 5,824,217 for such variations, the teachings of which are herein incorporated by reference in its entirety.

The screen be it a feed screen, filtrate screen or retentate screen may basically be a defined open volume or a porous single layer such as a screen *per se*.

One such open volume screen can be formed by one or more sealing rims or outer edge gaskets formed on a surface of an adjacent layer such as a membrane or endcap and thereby defines a volume of space between two adjacent layers such as an endcap layer and a membrane. This acts in the same manner as a screen and is therefore for the purposes of the invention considered to be a screen. In this embodiment, it is preferred that the rim or rims be formed of the same material and formed in the same way as the gaskets and have the same height dimensions as the gaskets to ensure that a complete seal is formed between the various layers. More particularly, the rim or rims are formed by injection molding.

Figure 7 shows an endcap 61, such as is made of a nonporous polyethylene sheet on which a rim 62 has been injection molded to form such a space when assembled next to another layer such as a membrane.

In addition to be used as a seal around a port or as a rim or rims to form a open space screen, one may also form various structures on or in the surfaces of the various layers to control flow distribution, residence time or other factors of the device or the fluid within the device.

While the invention has been largely explained in reference to a first preferred embodiment relating to the screens of a cassette type filtration device, its use is not so limited.

For example, it may be used with traditional filter holders which comprise two rings capable of being clamped together and holding a membrane between the two rings in a liquid tight sealing arrangement. The use of the thermoplastic elastomers as seals in that device is quite helpful in forming a liquid tight seal. If desired, the sealing surface of one or both holders

may have a groove, such as a dovetail or other undercut arrangement formed in its surface and the thermoplastic elastomer may be molded into the groove and made proud of that groove and surface so as to form a sealing device for the holder.

The invention may also be used to form gaskets 71 used to connect the filter device 72 to the manifold plate 73 as shown in Figure 8. These gaskets may be preformed or formed in place as desired. Preferably, they are formed in place so as to ensure that they do not dislodge from the device during assembly or become mis-aligned during assembly and thereby mis-sealed. If the seal is formed on a structure which is reused, it is preferred that the bond to the component be sufficient to ensure that the seal stays in place during normal use and handling, but is capable of being removed and replaced as is needed over time.

Alternatively, the invention may be used as shown in Figure 9 to form O-ring seals 81 used on cartridge filter devices 82 in lieu of the traditional silicone or PTFE resin O-rings. As discussed above they may be preformed or formed in place. The current cartridge housing design typically has a slight recess formed around the circumference of the device where it retains the O-ring. The O-ring of the present invention may be molded to that recess directly or if desired that recess can be modified to have an undercut or retention feature such as a dovetail to ensure that the O-ring is formed in-place and will stay in-place.

The screen, if used, may alternatively be a woven, nonwoven or porous structure such as a woven polyethylene, polypropylene, fiberglass, glass, carbon or polyester screen, a nonwoven screen such as spun bonded fabric or TYVEK® or TYPAR® paper. It may also be in the form of a scrim or as a porous film such as a highly porous membrane. Alternatively, it may be made from a film in which a series of holes, channels or openings are formed or it may be made of a cast grid like structure.

The membrane may be a microporous, ultrafiltration (UF), nanofiltration or reverse osmosis membrane formed of a polymer selected from olefins such as polyethylene including ultrahigh Molecular weight polyethylene, polypropylene, EVA copolymers and alpha olefins, metallocene olefinic polymers, PFA, MFA, PTFE, polycarbonate, vinyl copolymers such as PVC, polyamides such as nylon, polyesters, cellulose, cellulose acetate, regenerated cellulose, cellulose composites, polysulphone, polyethersulphone, polyarylsulphone, polyphenylsulphone, polyacrylonitrile, polyvinylidene fluoride (PVDF), and blends thereof. The membrane selected depends upon the application, desired filtration characteristics, particle type and size to be filtered and the flow desired.



The other filter components such as end caps, inlets, outlets, housings, spacers, retainers, manifolds, capsules, etc., to which a seal of the present invention may be applied, can be made of a variety of materials, such as metal, ceramic, glass or plastic. Preferably, the components are formed of metal such as stainless steel, especially 316 stainless steel or aluminum due to their relatively low cost and good chemical stability or more preferably plastics, such as polyolefins, especially polyethylene and polypropylene, homopolymers or copolymers, and ethylene vinyl acetate (EVA) copolymers; polycarbonates; styrenes; PTFE resin; thermoplastic perfluorinated polymers such as PFA; nylons and other polyamides; PET and blends of any of the above. When using a molded in place seal, it is preferred that the component to which the seal is bonded be compatible with and ensure a good adhesion between the components so that the seal remains as an integral part of the component to which it is bonded.

The seal is formed of any elastomeric material. The material does not need to be very elastic but it should have some ability to maintain the seal with the adjacent layers during flexion or compression. Preferably it has a durometer of from about 60 to about 100. Suitable materials include but are not limited to thermoplastics, such as polyethylene, polypropylene, EVA copolymers, alpha olefins and metallocene copolymers, PFA, MFA, polycarbonate, vinyl copolymers such as PVC, polyamides such as nylon, polyesters, acrylonitrile-butadienestyrene (ABS), polysulphone, polyethersulphone, polyarylsulphone, polyphenylsulphone, polyacrylonitrile, polyvinylidene fluoride (PVDF), and blends thereof, thermoplastic elastomers such as Santoprene® polymer, EPDM rubber, thermosets such as closed cell foamed urethanes, and rubbers, either natural or synthetic.

It is preferred that the material be a thermoplastic or thermoplastic elastomer so as to allow for its use in the preferred method of this invention, injection molding. One such preferred material is a SANTOPRENE® polymer with a durometer of about 80 available from Advanced Elastomer Systems of Akron, Ohio. Preferred thermoplastics include low density, linear low density, medium density and high density polyethylene, polypropylene and EVA copolymers.

The seal is formed preferably by molding or bonding of seal to a portion or component of the device. Preferably, the seal is injection molded to the component. Thermoplastic elastomers and thermoplastics are preferred for the injection molding process although thermosets, such as rubber or urethane may be used. The gasket may be formed on one or

both sides of the screen as desired. Preferably it is formed as one injection-molded piece on both sides of screen. To form such a gasket, two molds each corresponding to a half of the final gasket design are made and placed on opposite sides of feed screen in alignment with each other. Thermoplastic elastomers or molten thermoplastic or other selected seal material is then injected into either one or both mold pieces and fills the mold with the seal material, thus forming the desired gasket in place on the screen.

Alternatively, if desired, the seal may be pre-molded and attached to the opening in the screen layer by various means such as adhesives or a mechanical retention of the seal such as by a press fit of the seal within the opening of the screen (similar to that of a rubber grommet).

A module according to the present invention is typically formed in the following manner: a screen, preferably a feed screen is formed with a series of ports in at least one, preferably both of its outermost edges opposite each other. Seals according to the present invention are formed and secured around the desired ports.

In a tangential flow filtration apparatus using the screen or module containing such screen of the present invention, the feed, retentate and filtrate ports are arranged so that the incoming fluid feed to the apparatus enters at least one feed channel, passes through the feed screen layer(s) and either passes through a membrane to form a filtrate stream or is retained by a membrane to form a retentate stream. The retentate stream is removed from the device through the one or more retentate ports and the filtrate stream is removed through the one or more filtrate ports. If desired, one or more filtrate inlet ports and one or more filtrate outlet ports can be formed so that some filtrate is recycled to the filtrate layer inlet port to effect tangential flow on the filtrate side. This may also be done on the retentate side instead of on the filtrate side or on both sides to increase tangential flow efficiency of the device. By doing so, one may control the transmembrane pressure within the device.

In a dead end flow filtration apparatus of the present invention, the feed and filtrate ports are sealed from each other and only filtrate is recovered from the module.

Other uses and embodiments for the invention will be obvious to one of ordinary skill in the art and it is meant to encompass these embodiments in the present invention and claims.

## EXAMPLE 1

A TFF module was made with a feed screen having an injection molded thermoplastic elastomeric gasket made from Santoprene® 80 durometer elastomer and .005 inch in height from each side of the screen. One layer of a composite regenerated cellulose membrane, PL composite, a relatively easily compressible membrane available from Millipore Corporation, was used in the module.

A comparison module, known as a PELLICON® Maxi cassette, available from Millipore Corporation of Bedford, Massachusetts was constructed similarly to the one above, except that the feed screen seal of standard epoxy was used. This seal was flush with the surface of the screen.

Both were tested in a PELLICON® SS benchtop manifold, available from Millipore Corporation of Bedford, Massachusetts at 350 inlbs torque. Each was exposed to a series of 5 alternating cold/hot cycles using water as the fluid. The hot cycle was at a feed pressure of 60 psi and then a retentate pressure of 35 psi at 50°C for two hours. The cold cycle was static storage in a refrigerator at 5°C for 18 hours. Integrity of the seal in each cassette was tested at 10 psi intervals up to 110 psi between each cycle.

The integrity results were plotted in the graph of Figure 10 for both devices. As can be clearly seen the molded gasket device maintained its integrity throughout the test. The traditional cassette failed to achieve the high initial pressure resistance of the module of the present invention (80 vs 110psi) and it exhibited decreased sealing ability with increasing cycles.

The present invention has several advantages over the currently available devices.

First and foremost, it allows for the use of more compressible membranes than has been possible before, such as composite cellulose membranes. These membranes are highly efficient but due to their structure are easily compressible causing leakage to occur. The present invention overcomes the sealing problem created by such membranes thereby allowing for an entire new class of membranes to be used in filtration devices.

Second, it allows for the use of higher pressures in these applications, either with the traditional membranes or the newer more compressible membranes. Likewise, it is resilient in alternating hot/cold cycles which are quite common in filtration applications (cold for filtration, hot for inter batch cleaning). As the data clearly shows such thermal cycling has no effect on the performance of the device utilizing the current invention.

Third, it allows for different port sealing geometries other than circular, and overall smaller diameter sealing areas than is possible with glued ports.

It allows for the use of thicker screens and /or more open screens or filter membranes as there is no overfilling of the screens or membranes as occurs in gluing when using very open screens or membranes.

It can allow for the use of open volume spaces in lieu of a physical screen in a cassette format as it forms a rim/spacer between the adjacent layers that is traditionally filled with a screen.

It allows for the use of formed in place gaskets, sealing devices and O-rings with controlled formation of the devices and little if any spreading of the material beyond the desired area. This is something that is not possible with epoxies and urethanes today.

It also allows for the sealing devices which have an ease of formation and application, low extractables, low absorption/desorption of components from the fluid being filtered.

When used in the preferred embodiment of formed in place seals, one obtains an integral seal on the device which has several advantages in the ease of assembly and use, the assurance that the seal is always retained at the right location and cannot be mis-aligned or mis-sealed. Additionally, in these molded in place embodiments, the seal eliminates any dead space between the seal and the filter component to which it is bonded in which a microorganism such as a bacteria, yeast, mold or virus could otherwise grow and threaten the integrity and sanitary condition of the filter.

The use of thermoplastics and thermoplastic elastomers offer increased cleanliness and lower levels of extractables than that found with the current urethanes, epoxies or silicones used in such devices.

## WHAT WE CLAIM:

1) A filtration device comprising one or more filter layers and one or more openings, said openings having one or more sealing means for establishing a liquid tight seal around each of the one or more openings, said means being an elastomeric material selected from the group consisting of thermoplastics, thermoplastic elastomers, thermoset elastomers and rubber, natural and synthetic.

2) A feed screen for a filter device comprising a screen containing a plurality of openings, said screen having a relatively uniform thickness and a series of two or more ports along at least of its peripheral edges, at least one of said ports having a molded gasket which has a thickness greater than that of the screen and said thickness of said gasket extends from at least one side of said screen.

3) The device of claim 1 wherein the sealing means is in a form selected from the group consisting of a gasket, an O-ring and a sealing device.

4) The screen of claim 2 wherein the screen is formed of an elastomeric material selected from the group consisting of thermoplastics, thermoplastic elastomers, thermoset elastomers and rubber, natural and synthetic.

5) The screen of claim 2 wherein the gasket extends at least 0.001 inch above at least one side of the screen.

6) The screen of claim 2 wherein the gasket extends at least 0.002 inch above at least one side of the screen.

7) The screen of claim 2 wherein the gasket extends at least 0.005 inch above at least one side of the screen.

8) The screen of claim 2 wherein the gasket extends from about 0.001 to about 0.015 inch above at least one side of the screen.

9) The screen of claim 2 wherein the gasket is formed by injection molding.

10) A filtration module comprising at least one membrane layer, at least one feed screen layer and at least one filtrate screen, said at least one feed screen layer and said at least one filtrate layer having one or more ports formed in at least one of its edges and said layers being arranged on opposite sides of the membrane to insure fluid flows through a port on the feed screen layer into the feed screen layer, from the feed screen layer through the membrane and into the filtrate layer and through the one or more ports of the filtrate layer to an

exit from the module, wherein the one or more ports of the feed screen and filtrate layer contain a molded gasket which has a thickness greater than that of the screen and said thickness of said gasket extends from at least one side of said layer.

11) The module of claim 10 wherein the gasket extends from about 0.001 to about 0.015 inch above at least one side of the screen.

12) The module of claim 10 wherein the gasket extends from about 0.001 to about 0.015 inch above each side of the screen.

13) The module of claim 10 wherein the gasket extends from both sides of the screen.

14) The module of claim 10 wherein the gasket is formed of an elastomeric material selected from the group consisting of thermoplastics, thermoplastic elastomers, thermoset elastomers and rubber, natural and synthetic.

15) The module of claim 10 wherein gasket is formed by injection molding.

16) The module of claim 10 wherein the gasket is in a shape selected from the group consisting of a circle, oval and polygon.

17) The module of claim 10 wherein the gasket is in the shape of a polygon and the polygon is selected from the group consisting of triangles, rectangles, pentagons, hexagons, heptagons, octagons, nonagons and decagons.

18) The module of claim 10 wherein the height of the gasket is also used to vary the channel height of the feed screen.

19) The module of claim 10 wherein the height of the gasket is also used to vary the channel height of the filtrate layer.

20) The module of claim 10 wherein the module is capable of withstanding pressures of from about 50 to about 110 psi without leaking.

21) The module of claim 10 wherein the filter layer is made of a material selected from the group consisting of olefins, metallocene olefinic polymers, PFA, MFA, PTFE, polycarbonate, vinyl copolymers, polyamides, polyesters, cellulose, cellulose acetate, regenerated cellulose, cellulose composites, polysulphone, polyethersulphone, polyarylsulphone, polyphenylsulphone, polyacrylonitrile, polyvinylidene fluoride (PVDF), and blends thereof.

22) The module of claim 10 wherein one or more sealing rims is formed upon the surface of the endcap layer.

23) The device of claim 1 wherein means is one or more structures formed on a surface of the device from a molded thermoplastic or thermoplastic elastomer.

24) The device of claim 1 wherein the sealing means is formed as a gasket.

25) The device of claim 1 wherein the sealing means is formed as an O-ring.

26) The device of claim 1 wherein the sealing means is formed as a sealing rim around at least a portion of the periphery of a surface of one or more of the device components.

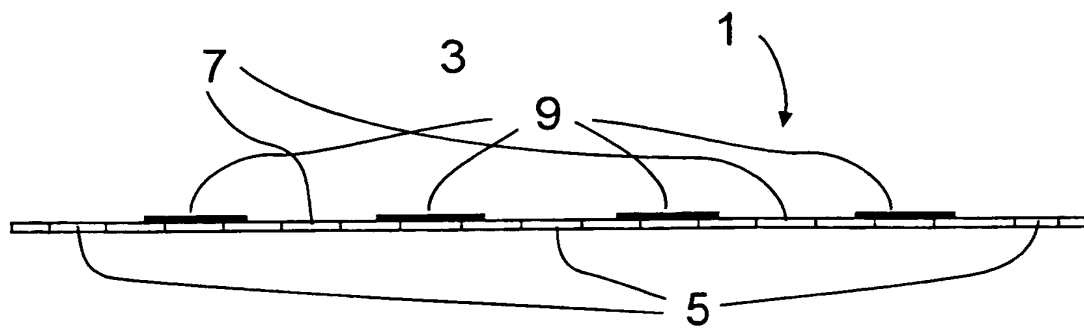


Fig. 1

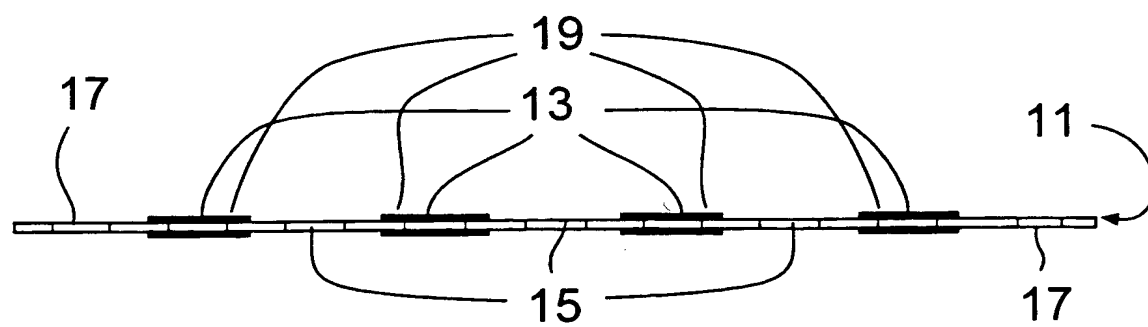


Fig. 2



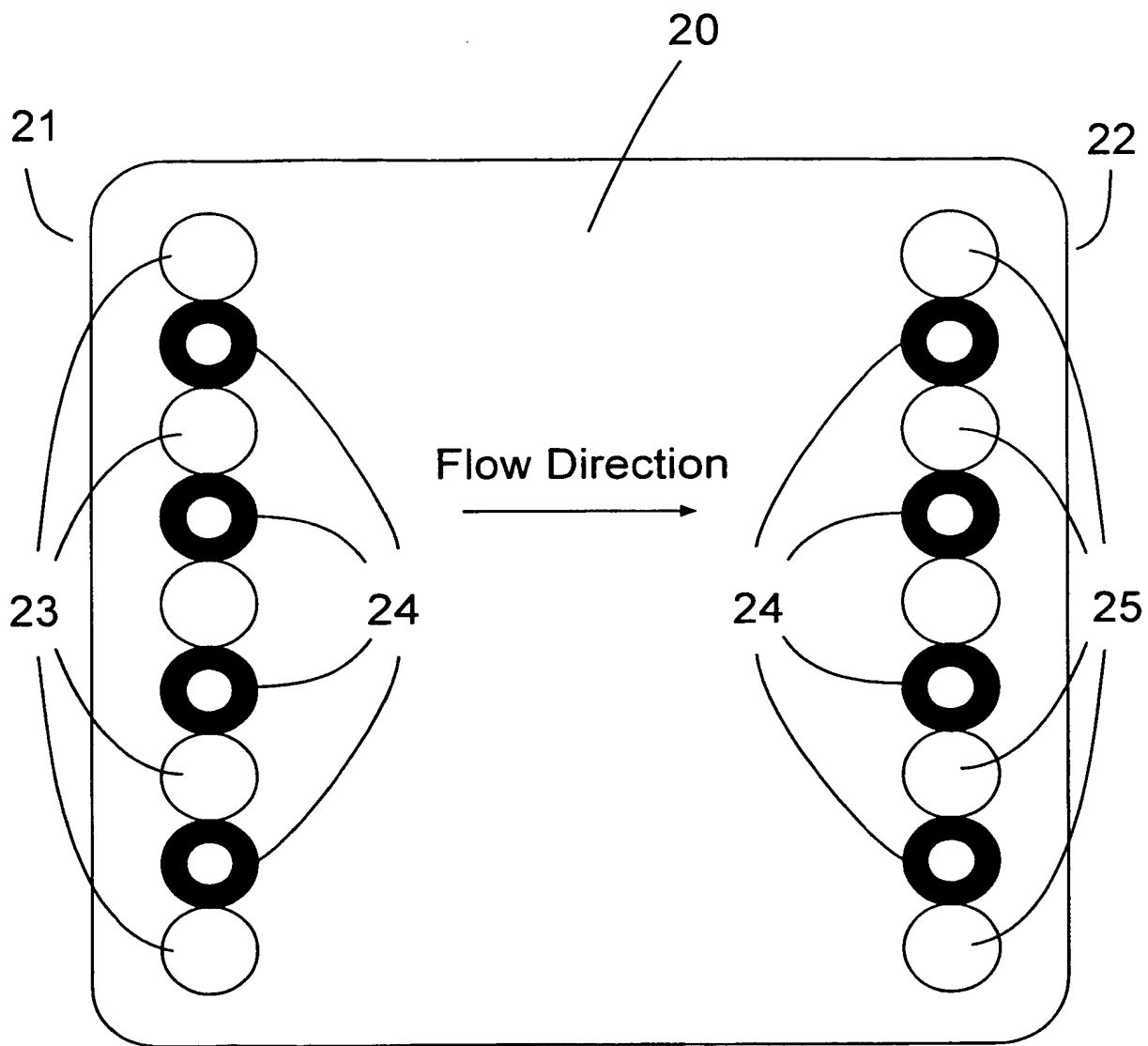


Fig. 3

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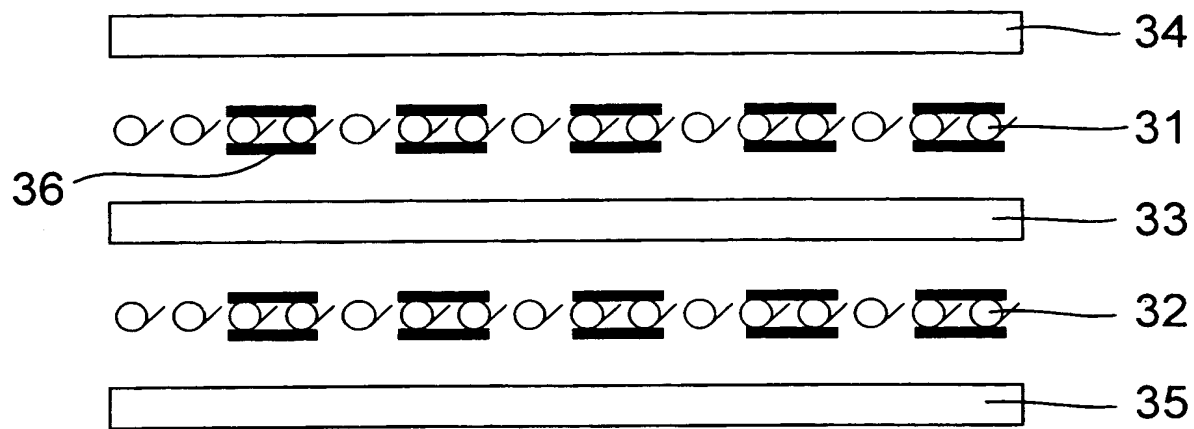


Fig. 4

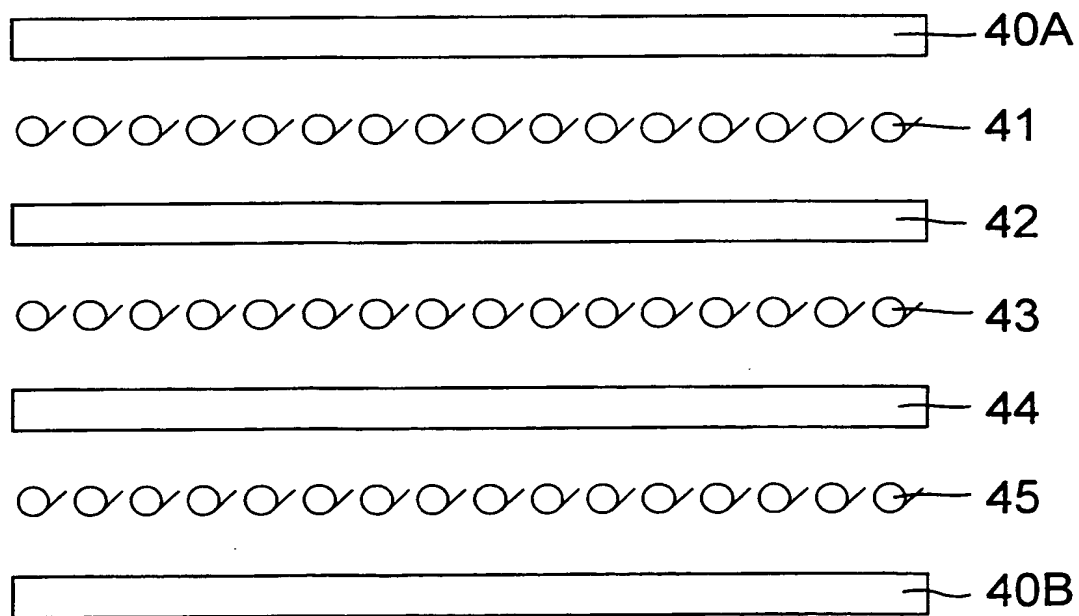


Fig. 5

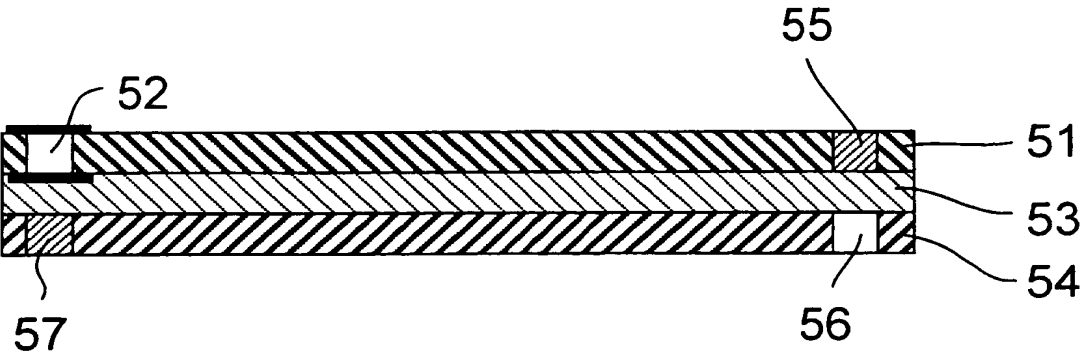


Fig. 6

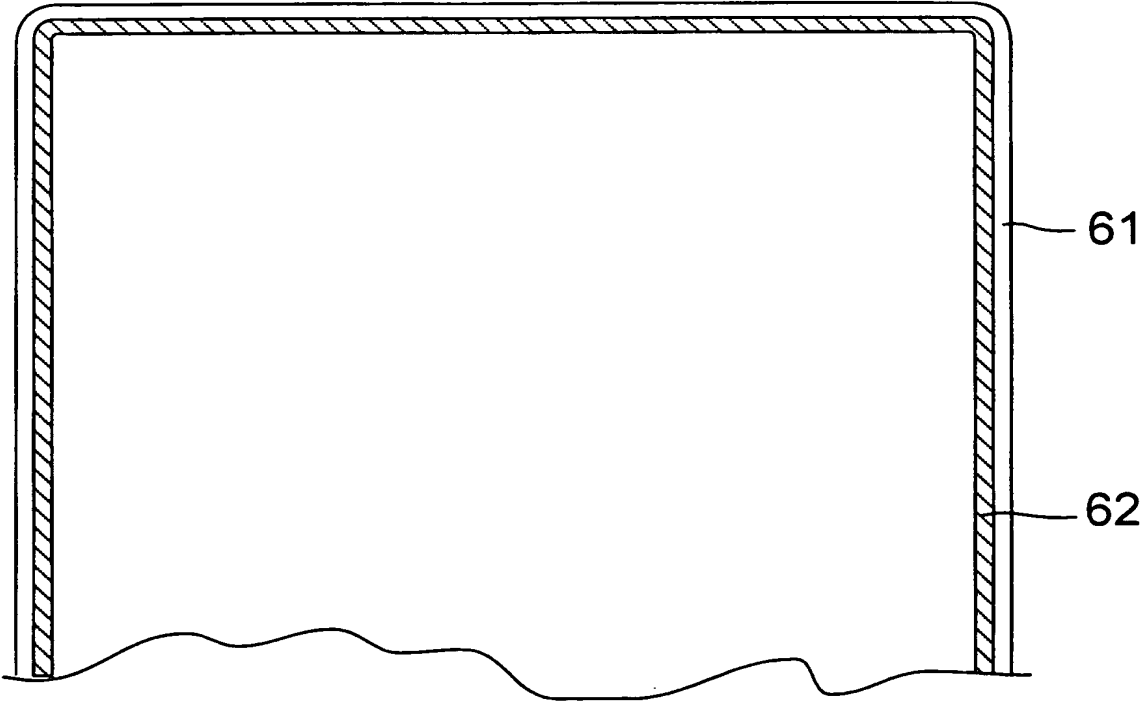


Fig. 7

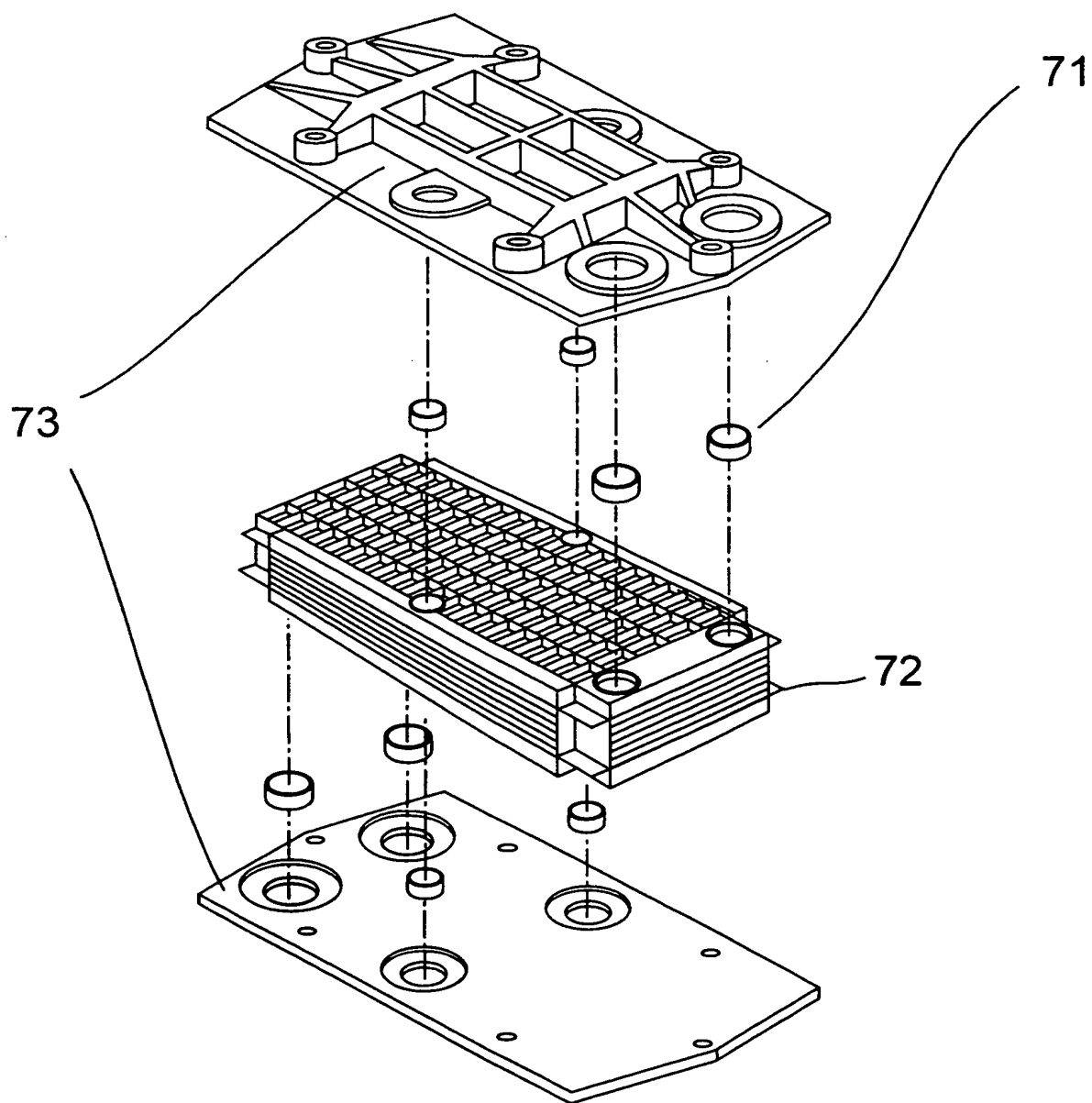


Fig. 8

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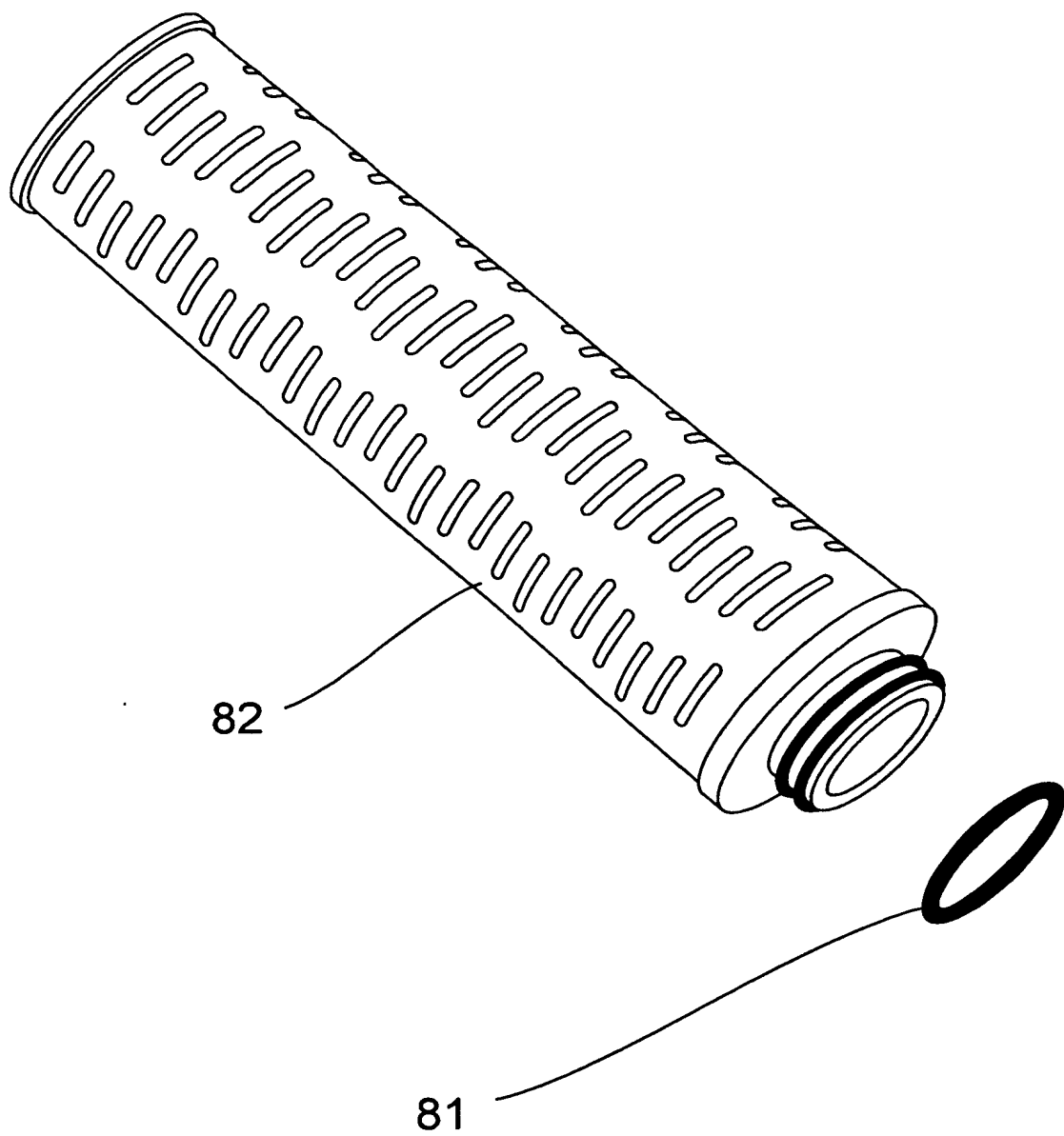


Fig. 9

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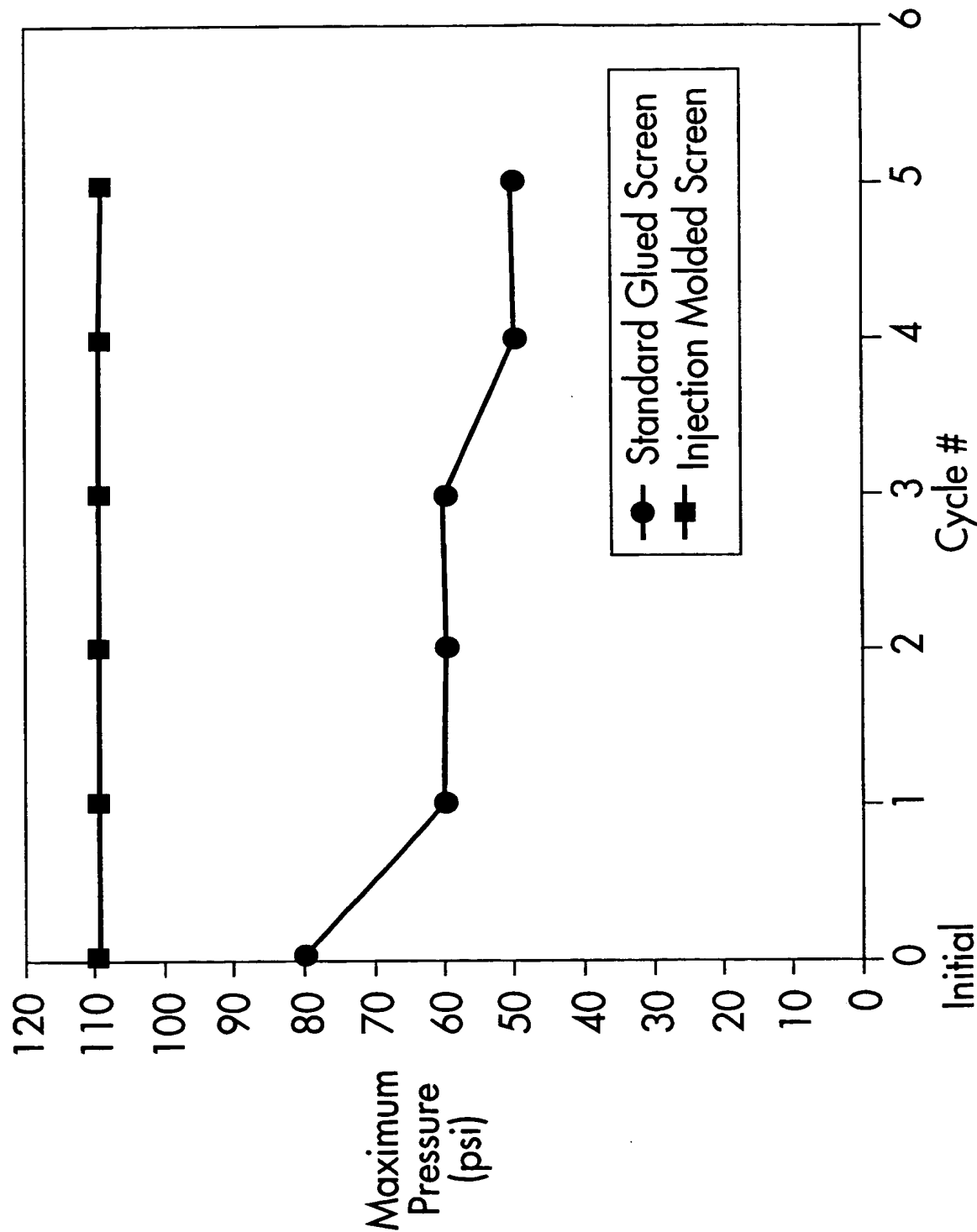


Fig. 10

# INTERNATIONAL SEARCH REPORT

Ir. ational Application No

PCT/US 00/17076

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 B01D35/30 B01D63/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B01D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 230 812 A (WILLIAMS) 27 July 1993 (1993-07-27) column 2, line 5 -column 5, line 7 ---	1,3,24
X	EP 0 470 440 A (GILARDINI S.P.A.) 12 February 1992 (1992-02-12) column 2, line 35 -column 5, line 52 ---	1,3, 23-26
X	US 5 034 124 A (KOPF) 23 July 1991 (1991-07-23) column 17, line 25 -column 18, line 5 column 19, line 56 -column 20, line 14 ---	1-26
X	US 5 445 737 A (ONDRICK) 29 August 1995 (1995-08-29) column 3, line 40 -column 5, line 37 -----	1-26

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

17 April 2001

Date of mailing of the international search report

25 April 2001 (25.04.01)

Name and mailing address of the ISA

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Doolan, G

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 00/17076

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.



**FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1 3 23-26

a filtration device

2. Claims: 2 4-22

a feed screen (for a filter device) or a filtration module

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/17076

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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